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(54) **MULTIPIECE ALLOGRAFT IMPLANT**

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(57) **ABSTRACT**

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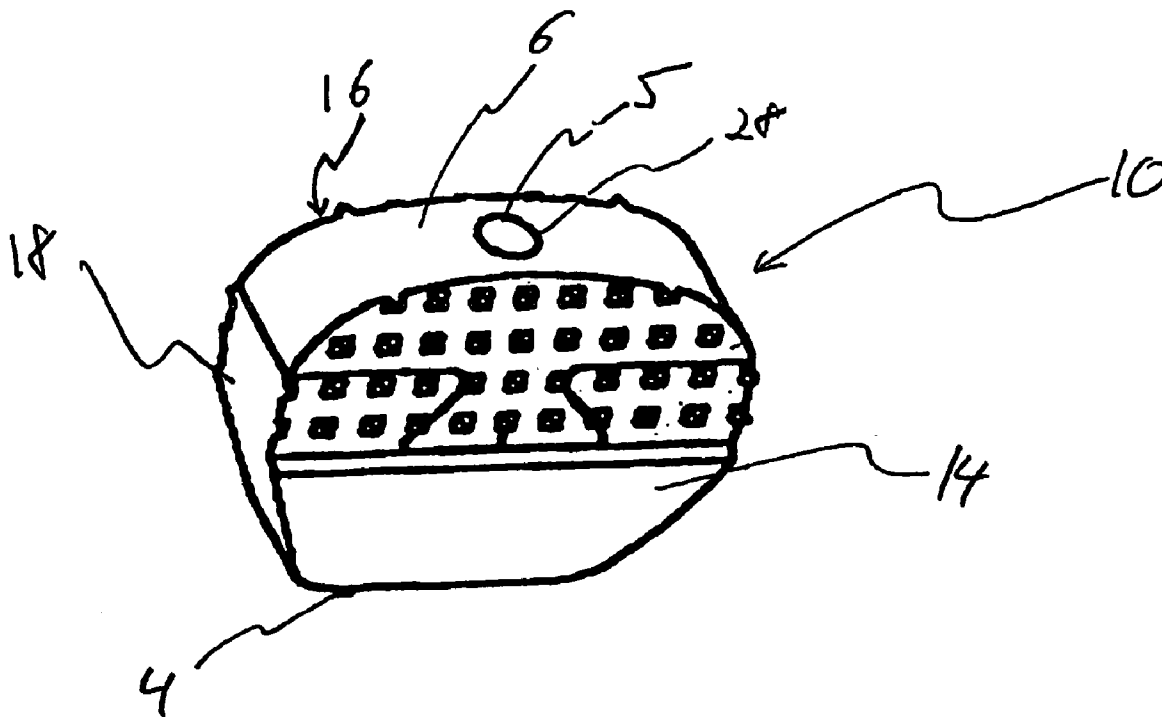
An allogenic implant for use in intervertebral fusion is formed from two parts. The first part, composed of cortical bone, provides mechanical strength to the implant, allowing the proper distance between the vertebrae being treated to be maintained. The second part, composed of cancellous bone, is ductile and promotes the growth of new bone between the vertebrae being treated and the implant, thus fusing the vertebrae to the implant and to each other. The implant is sized and shaped to conform to the space between the vertebrae. Teeth formed on the superior and inferior surfaces of the implant prevent short-term slippage of the implant.

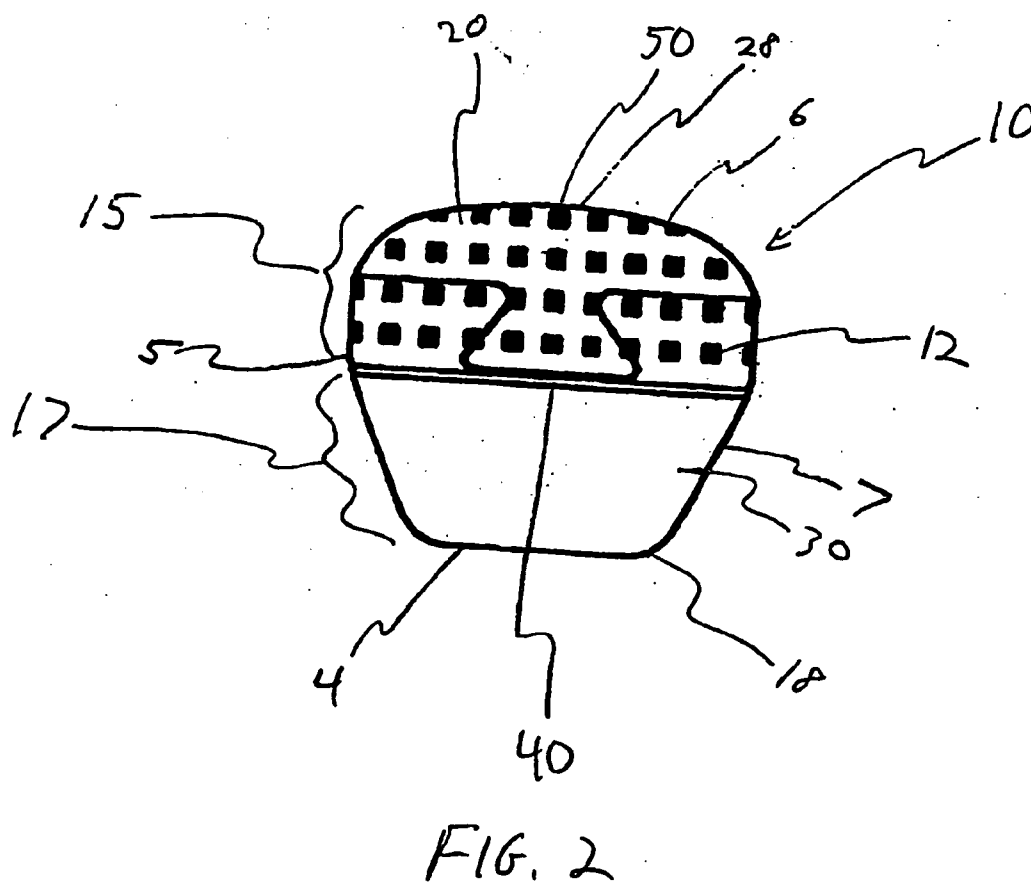
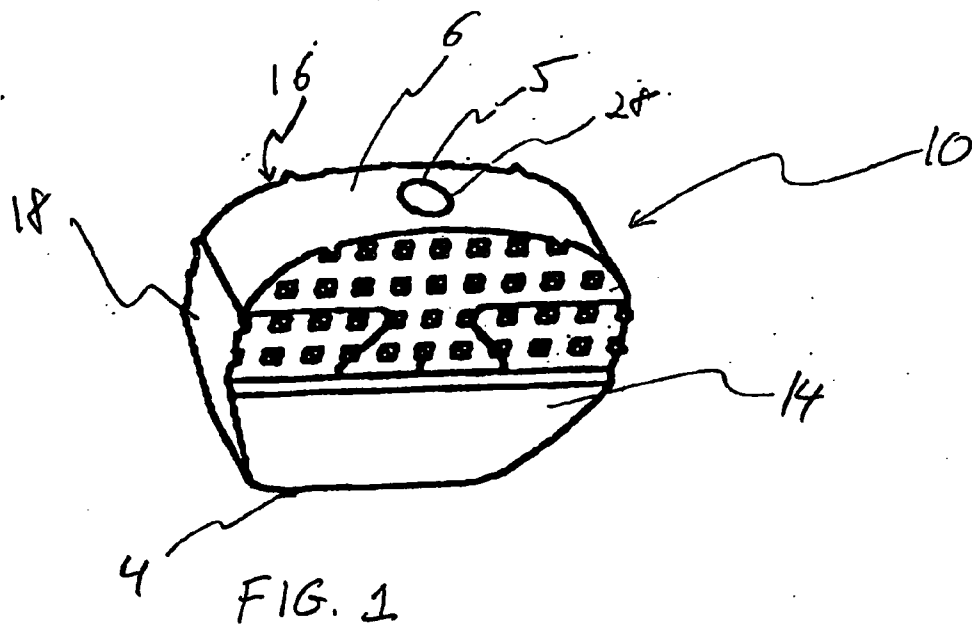
(21) Appl. No.: **10/931,788**

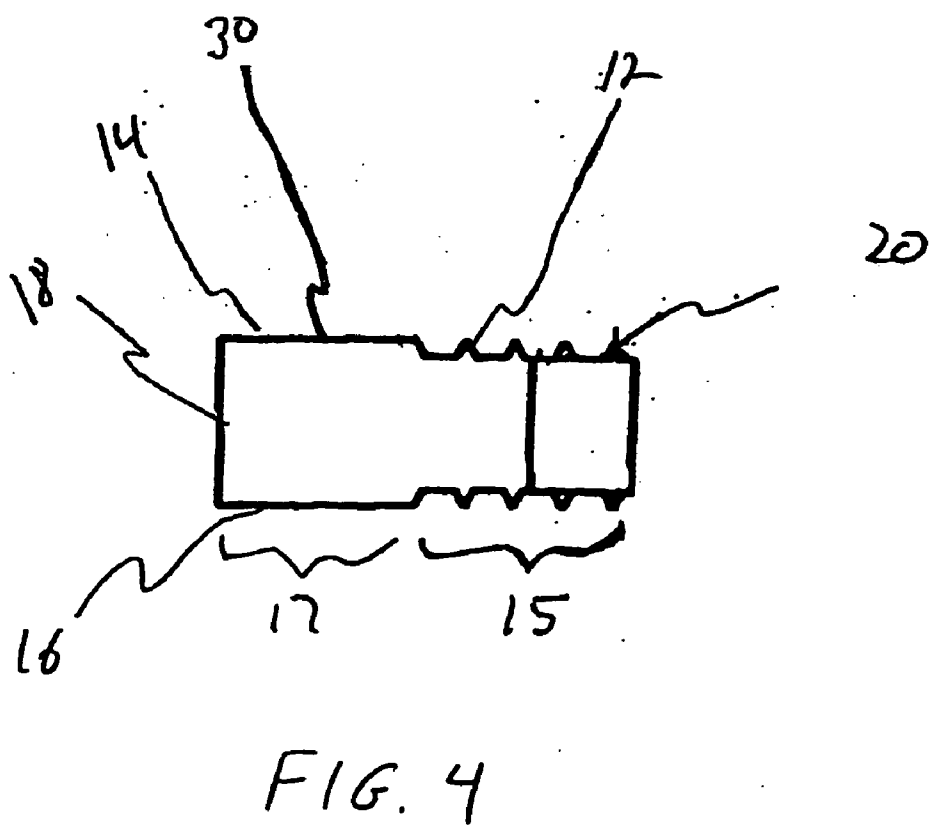
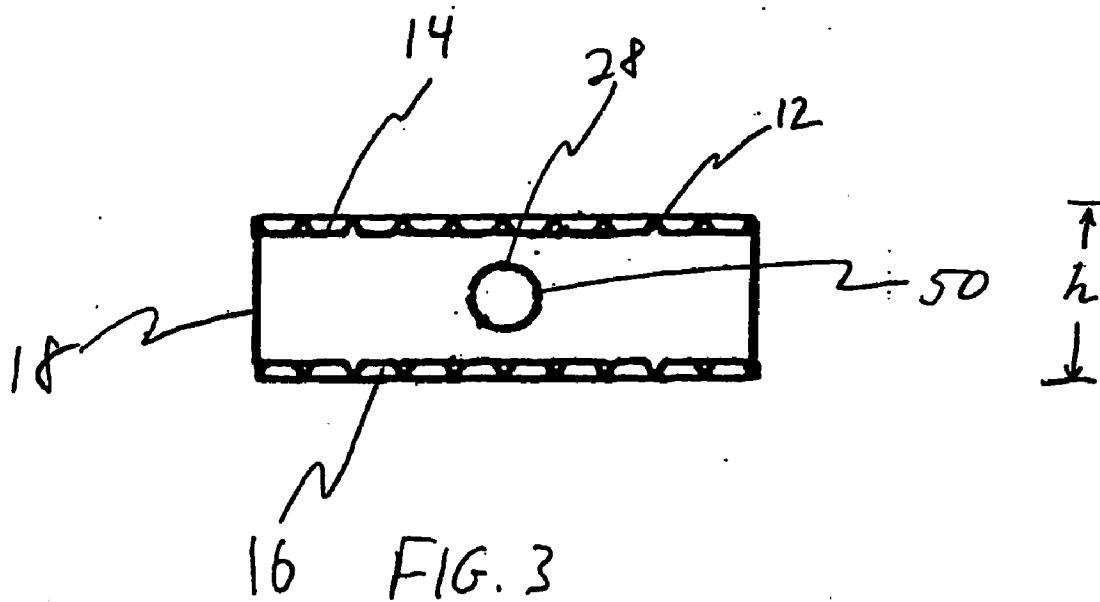
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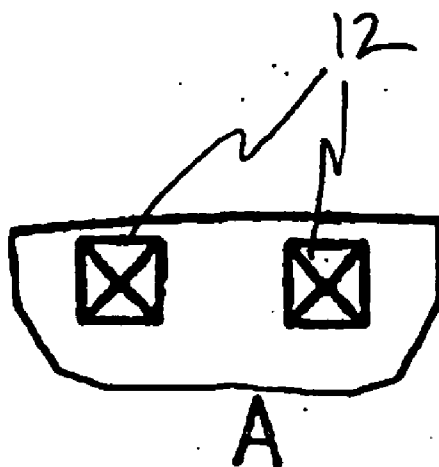


FIG. 5

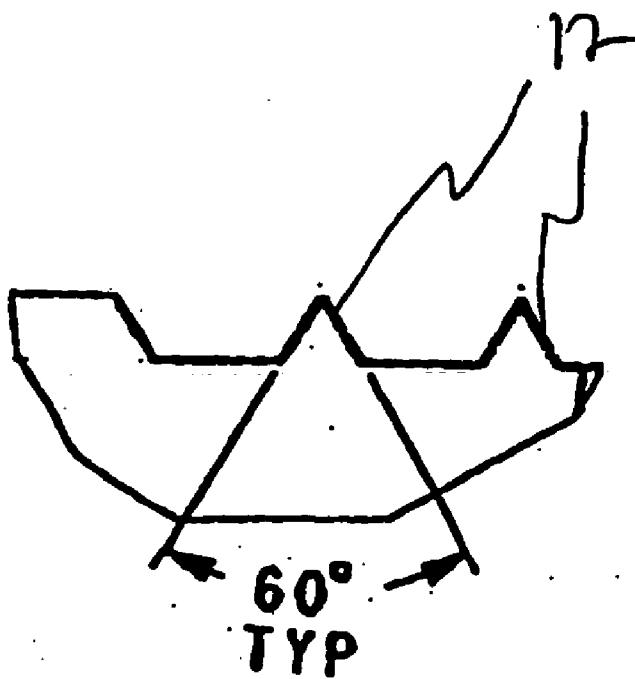
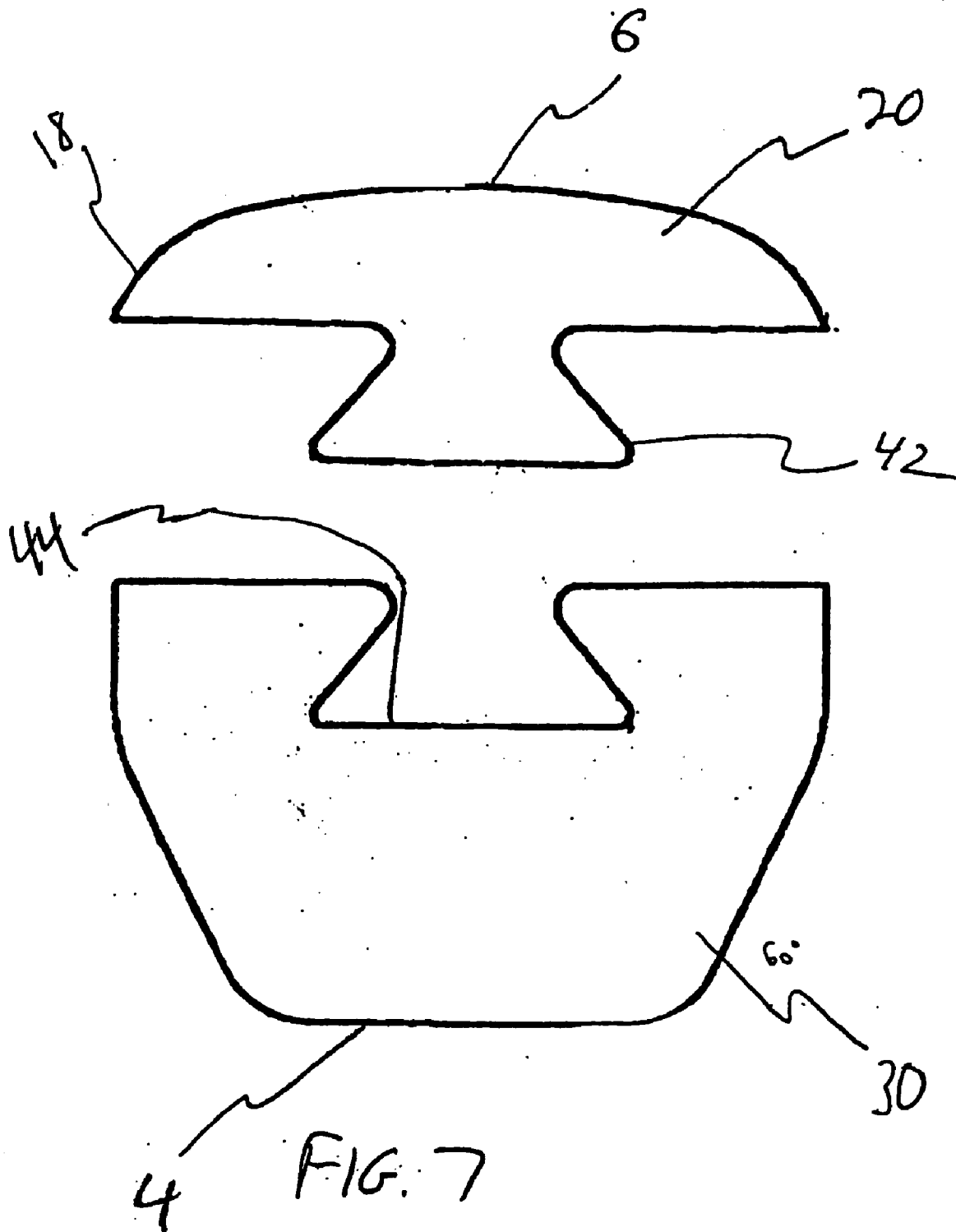


FIG. 6



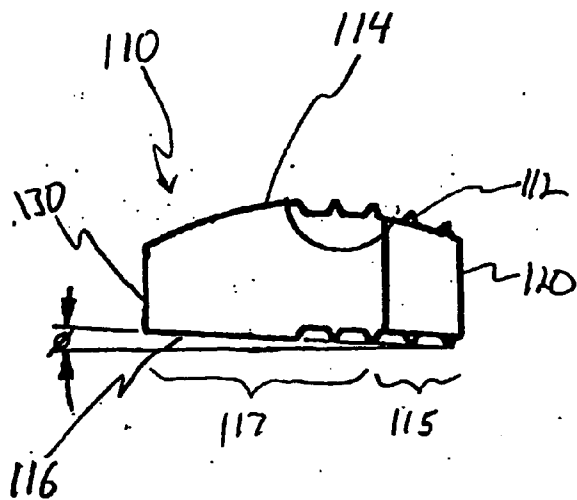


FIG. 10

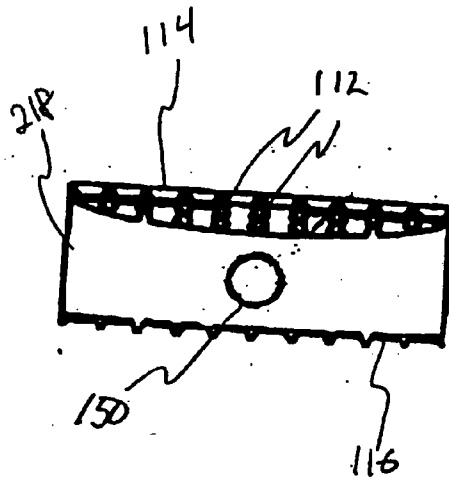


FIG. 11

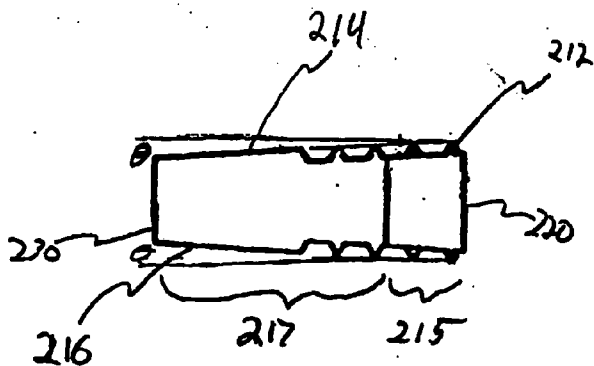


FIG. 8

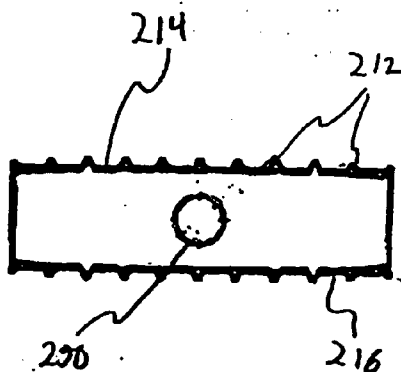


FIG. 9



FIG. 12

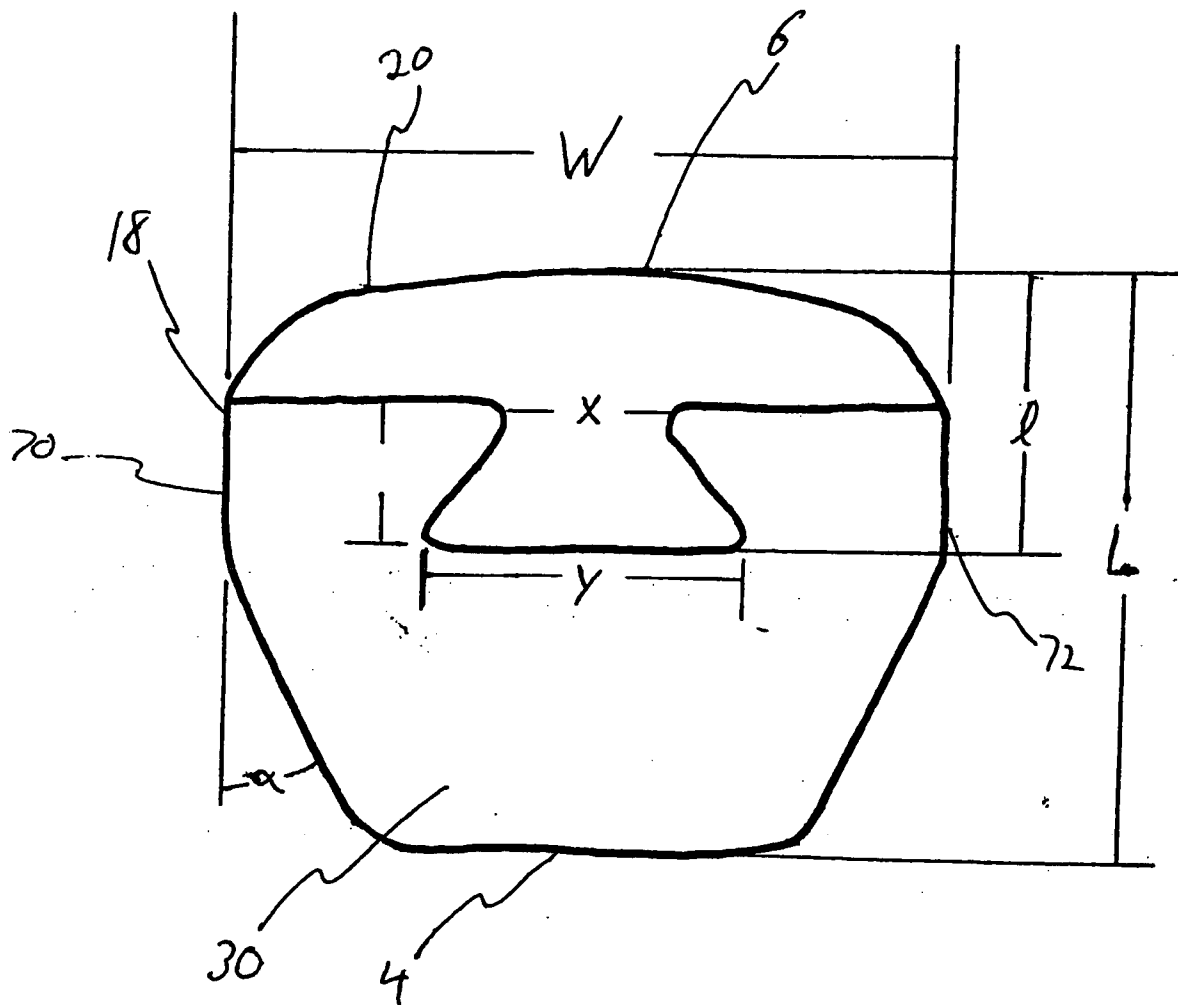


FIG. 13

MULTIPIECE ALLOGRAFT IMPLANT

FIELD OF THE INVENTION

[0001] The present invention is directed to an allogenic implant and, more particularly, to an allogenic intervertebral implant for the fusion of vertebrae.

BACKGROUND OF THE INVENTION

[0002] A number of medical conditions, such as compression of spinal cord nerve roots, degenerative disc disease, and trauma can cause severe back pain. Intervertebral fusion is a surgical method of alleviating back pain. In intervertebral fusion, two adjacent vertebral bodies are fused together by removing the affected intervertebral disc and inserting an implant that would allow for bone to grow between the two vertebral bodies to bridge the gap left by the removed disc.

[0003] A number of different implants and implant materials have been used for fusion with varying success. Current implants for intervertebral fusion include metallic cages and allografts. Metallic cages suffer from the disadvantage of requiring drilling and tapping of the vertebral endplates for insertion. In addition, the incidence of subsidence in long term use is not known. Due to MRI incompatibility of metallic cages, determining fusion is problematic.

[0004] Allografts are sections of bone taken from the diaphysis of a long bone, such as the radius, ulna, fibula, humerus, tibia, or femur of a donor. A cross-section of the bone is taken and processed using known techniques to preserve the allograft until implantation and reduce the risk of an adverse immunological response when implanted. For example, U.S. Pat. No. 4,678,470 discloses a method for processing a bone grafting material which uses glutaraldehyde tanning to produce a non-antigenic, biocompatible material. Allografts have mechanical properties which are similar to the mechanical properties of vertebrae even after processing. This prevents stress shielding that occurs with metallic implants. They also promote the formation of bone, i.e., osteoconductive, and are also MRI compatible so that fusion can be more accurately ascertained. Although the osteoconductive nature of the allograft provides a biological interlocking between the allograft and the vertebrae for long term mechanical strength, initial and short term mechanical strength of the interface between the allograft and the vertebrae needs to be addressed to minimize the possibility of the allograft being expelled after implantation.

[0005] Most allografts are simply sections of bone which, although cut to the approximate height of the disc being replaced, have not been sized and/or machined on the exterior surface to have a uniform shape. As a result, the fusion of the vertebral bodies does not occur in optimal anatomic position or in a consistent manner along the surface of the endplates. While a surgeon may do some minimal intraoperative shaping and sizing to customize the allograft for the patient's spinal anatomy, significant shaping and sizing of the allograft during the procedure is not possible due to the nature of the allograft. Even if extensive shaping and sizing were possible, a surgeon's ability to manually shape and size the allograft to the desired dimensions is limited.

[0006] With respect to the overall structure of a given bone, the mechanical properties vary throughout the bone.

For example, a long bone (leg bone) such as the femur has both cortical bone and cancellous bone. Cortical bone, the compact and dense bone that surrounds the marrow cavity, is generally solid and thus carries the majority of the load in long bones. Cancellous bone, the spongy inner bone, is generally porous and ductile, and when compared to cortical bone is only about one-third to one-quarter as dense, one-tenth to one-twentieth as stiff, but five times as ductile. While cancellous bone has a tensile strength of about 10-20 MPa and a density of about 0.7, cortical bone has a tensile strength of about 100-200 MPa and a density of about 2. Additionally, the strain to failure of cancellous bone is about 5-7%, while cortical bone can only withstand 1-3% strain before failure. It should also be noted that these mechanical characteristics may degrade as a result of numerous factors such as any chemical treatment applied to the bone material, and the manner of storage after harvesting but prior to implantation (i.e. drying of bones).

[0007] Notably, implants of cancellous bone incorporate more readily with the surrounding host bone, due to the superior osteoconductive nature of cancellous bone as compared to cortical bone. Furthermore, cancellous bone from different regions of the body is known to have a range of porosities. Thus, the design of an implant using cancellous bone may be tailored to specifically incorporate material of a desired porosity.

[0008] There is a need for an allograft that properly utilizes the different properties of cortical and cancellous bone to improve stability and to promote growth of new bone to fuse the vertebrae being treated during intervertebral fusion.

SUMMARY OF THE INVENTION

[0009] The present invention relates to an allogenic intervertebral implant for use when surgical fusion of vertebral bodies is indicated. The implant preferably comprises a wedge or plug conforming in size and shape with the end plates of adjacent vertebrae and has a plurality of teeth positioned on the top and bottom surfaces for interlocking with the adjacent vertebrae. The teeth preferably have a pyramid shape or a saw-tooth shape.

[0010] The implant preferably is comprised of two or more parts. At least the first part is preferably composed of cortical bone, while at least the second part is preferably composed of cancellous bone. The implant is configured so that when inserted between the vertebrae to be treated, the cortical and cancellous parts of the allograft are positioned so that the different properties possessed by the cortical and cancellous bone may be utilized effectively. The cortical part of the allograft is aligned with the vertebrae so that it bears the majority of the forces exerted on the implant, while the cancellous bone section promotes the growth of new bone with the implant to allow the vertebrae being treated to fuse with the allograft and each other.

[0011] The two or more sections preferably are attached by a dovetail joint. One or more pins may also be used to prevent the two sections from sliding out of connection with each other. The pins may be made of allogenic bone. Preferably the two or more pieces or sections are aligned so that they are side by side when inserted between vertebrae.

[0012] The implant preferably has teeth that are formed at least in the cortical section of the allograft. Teeth formed

from cortical bone, being much harder and stiffer than cancellous bone, are more effective in keeping the implant from being displaced. Furthermore, since the cortical part of the implant is where most of the load bearing occurs, teeth formed in this part have the greatest ability to grip into the vertebrae surfaces. Teeth may also be formed in portions of or the entire cancellous bone section or sections.

[0013] The implant may take on various profiles and exterior geometries, depending upon the area of the spine that is to be treated. The implant may further be shaped with various thicknesses, to maintain the proper distance between the vertebrae being treated.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 is a perspective view of an exemplary embodiment of the implant according to the present invention.

[0015] FIG. 2 is a top view of the embodiment of FIG. 1.

[0016] FIG. 3 is a back view of the embodiment of FIG. 1.

[0017] FIG. 4 is a side view of the embodiment of FIG. 1.

[0018] FIG. 5 is a partial top view of the embodiment of FIG. 1.

[0019] FIG. 6 is a partial side view of the embodiment of FIG. 1.

[0020] FIG. 7 is a top exploded view of the implant of FIG. 1.

[0021] FIG. 8 is a side view of a second exemplary embodiment of an implant in accordance with the present invention.

[0022] FIG. 9 is a back view of the embodiment of FIG. 8.

[0023] FIG. 10 is a side view of a third exemplary embodiment of an implant in accordance with the present invention.

[0024] FIG. 11 is a back view of the embodiment of FIG. 11.

[0025] FIG. 12 is a partial side view of an alternative teeth formation for the implant of FIGS. 7, 8, and 10.

[0026] FIG. 13 is a top view showing representative dimensions of the embodiment of FIGS. 1, 8, and 10.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0027] FIG. 1 shows a perspective view of a first embodiment of an intervertebral allograft spacer or implant 10 according to the present invention. Implant 10 preferably is shaped to conform in size and shape with at least a portion of the end plates of the vertebrae between which implant 10 is to be used. The outer periphery of implant 10 may be sided and shaped to match the outer periphery of the end plates of the vertebrae between which the implant 10 is to be used. Alternatively the outer periphery of the implant 10 may be sided and shaped to match only a portion of the outer periphery of the end plates of the vertebrae, or it may have

an outer periphery that may not match the peripheral shape of the end plates of the vertebrae at any location.

[0028] Implant 10 generally comprises a superior surface 14, an inferior surface 16, and an exterior surface 18. Superior surface 14 and inferior surface 16 further may comprise toothed sections 15 and flat sections 17. Toothed sections 15 of superior surface 14 and inferior surface 16 may be generally of the same size and shape, with toothed sections 15 being formed towards anterior end 6 and flat sections 17 being formed towards posterior end 4.

[0029] Implant 10 preferably is formed by the connection of first part 20 and second part 30. First part 20 preferably is formed from cortical bone. Second part 30 preferably is composed of cancellous bone. First part 20 and second part 30 preferably are connected by a dovetail joint 40 so that first part 20 and second part 30 are connected side by side to each other. First part 20 and second part 30 may further comprise first hole 28 and first hole 38 (not shown) through which pin 50 may be inserted to prevent sliding of first part 20 and second part 30 along dovetail joint 40. First hole 28 may be formed such that it goes through the entire length of first part 20. Second hole 38 may be formed such that it goes through the entire length of second part 30 or only a portion thereof. Pin 50 may be inserted through the entirety of first part 20 and second part 30 or through only a portion thereof. Pin 50 may be sized such that pin 50 protrudes from either first hole 28 or second hole 38 when pin is fully inserted. In this case, any excess portion of pin 50 protruding from first hole 28 or second hole 38 may be removed by further processing. Alternatively, pin may be sized so that it does not extend all the way through both first hole 28 and/or second hole 38.

[0030] As shown in FIG. 7, male portion 42 of dovetail joint 40 may be formed on first part 20, and female portion 44 of dovetail joint 40 may be formed on second part 30. However, in an alternative embodiment, male portion 42 may be formed on second part 30 and female portion 44 may be formed on first part 20. Male portion 42 may have a length z that preferably is approximately 3 mm, a first width x at its narrowest point that preferably is approximately 3.1 mm, and a second width y at its widest point that preferably is approximately 6.3 mm, with female portion 44 having corresponding dimensions (see FIG. 13). In an alternative embodiment, female portion 44 has dimensions that are slightly smaller than the dimensions of male portion 42, thus creating an interference fit between male portion 42 and female portion 44. However, it is to be understood that male portion 42 and female portion 44 may have different dimensions than the ones described above without departing from the spirit and scope of the invention. In addition, more than one dovetail connection, and/or more than one pin connection may be used in forming implant 10. Furthermore, the pin may be inserted in alternative locations. Furthermore, other methods of connecting first part 20 and second part 30 may be used without departing from the spirit and scope of the invention.

[0031] Implant 10 has a plurality of teeth 12 formed within toothed sections 14, 16 that preferably provide a mechanical interlock between implant 10 and the end plates of the vertebrae to be treated. Preferably, as shown in FIGS. 5 and 6, teeth 12 may be pyramid shaped, with the angle formed from the tip to the base being approximately 60 degrees.

Alternatively, teeth **12** may have a saw tooth shape with the saw tooth running in the anterior-posterior direction (see FIG. 12).

[0032] As seen in FIGS. 1 to 4, the majority of toothed sections **15** are comprised of the entire superior surface **14** and inferior surface **16** of first part **20**. Because these teeth **12** are preferably formed from cortical bone, teeth **12** have sufficient strength and hardness to impale themselves into the vertebrae surfaces and provide an enhanced interlock with the adjacent vertebrae. Teeth **12** may also be formed in second part **30** in order to simplify the manufacturing process (further described below), although these teeth **12** do not have the same strength and hardness of teeth **12** formed in first part **20**.

[0033] Teeth **12** are generally arranged in a two-dimensional array or pattern. In a preferred embodiment, teeth **12** are arranged in an array composed of evenly spaced rows and columns. However, it can be readily seen by those skilled in the art that teeth **12** may be arranged within toothed sections **15** in many different ways, without departing from the spirit and scope of the present invention.

[0034] Flat sections **17** preferably are comprised entirely upon superior surface **14** and inferior surface **16** of second part **30**. Flat sections **17**, being formed of cancellous bone, are more ductile than toothed sections **15** and will deform to conform to the surface contours of the vertebrae being treated. This further ensures an optimal fit of implant **10** between the vertebrae and promotes fusion of the vertebrae with the implant **10**, without excessive contouring of the surfaces of implant **10**.

[0035] Ideally, an intervertebral implant comprises as much cancellous bone as possible while providing sufficient support to maintain the proper spacing between the vertebrae being treated, so that the promotion of new bone growth is maximized. By properly sizing and shaping first section **20** of implant **10**, composed of cortical bone, and by properly aligning first part **20** so that it is subject to the majority of forces exerted on implant **10** by the vertebrae being treated, implant **10** has sufficient strength to maintain the proper distance between the vertebrae, while minimizing the amount of cortical bone required. The rest of implant **10**, being composed of cancellous bone (i.e., second part **30**), can then be used more advantageously to promote the growth of new bone between the vertebrae being treated, thus providing long-term stability to the vertebrae and implant **10**. Because most of the load bearing of implant **10** occurs on first part **20**, the effectiveness of teeth **12** formed in first part **20** to grip into the surfaces of the vertebrae is enhanced. The application of force on first part **20**, and therefore teeth **12**, enhances the ability of teeth **12** to penetrate into and grip the vertebrae surfaces, thus preventing short-term slippage of implant **10** until implant **10** is fused with the vertebrae by the growth of new bone.

[0036] Thus, implant **10** takes advantage of the different properties of cortical and cancellous bone to improve the use of allogenic bone in the surgical method of intervertebral fusion. Implant **10** may be customized according to the needs of the user, as different combinations of cortical and cancellous bone, may be selected, depending upon the properties desired. An implant **10** in accordance with the present invention also allows for more efficient use of available material, as pieces of allogenic bone that would otherwise not be large enough to form a suitably sized implant may be used instead to form a part of implant **10**.

[0037] In the preferred embodiment shown in FIGS. 1 to 4, superior surface **14** and inferior surface **16** are parallel

with each other. However, in certain areas of the spine, it may be desirable for implant **10** to have inclined and/or curved surfaces in order to restore the natural curvature of the spine after the affected disc has been removed. For example, as shown in FIGS. 8 and 9, implant **220** may have a wedge shaped profile, with superior surface **214** and inferior surface **216** each defining an angle θ . Angle θ may preferably be within the range of about 2 to about 5 degrees, and preferably is about 3.5 degrees. In yet another embodiment, as shown in FIGS. 10 and 11, inferior surface **116** defines an angle ϕ , while superior surface **114** is curved to conform to the surface of the topography of the vertebral end plates. Angle ϕ may preferably be within the range of about 2 to about 5 degrees, and preferably is about 3.5 degrees. The radius of curvature of superior surface **114** may be within the range of about 8 to about 25 mm, and preferably is about 14 mm.

[0038] In the above illustrated embodiments, and as further illustrated in FIG. 13, exterior surface **18** is formed so that posterior end **4** is flat, while anterior end **6** is curved. Anterior end **6** has a radius of curvature preferably within the range of about 15 to about 25 mm, and preferably is about 20 mm. The length L of implant **10** from anterior end **6** to posterior end **4** is preferably within the range of about 10 to about 15 mm, and preferably is about 12.5 mm. First part **20** has a length l (including male section **42**) preferably within the range of about 4 to about 8 mm, and preferably is about 6 mm. The width W of implant **10** from the medial surface **70** to the lateral surface **72** at its widest point is preferably within the range of about 10 to about 18 mm, and preferably is about 15 mm. Furthermore, sides **5** of exterior surface **18** that correspond with toothed sections **15** are parallel to each other, while sides **7** of exterior surface **18** that correspond with flat sections **17** are angled in towards posterior end **4** at angle α . Angle α is preferably within the range of about 20 to about 40 degrees, and preferably is about 30 degrees. With this geometry, implant **10** may ideally be used between cervical vertebrae. However, it can be readily seen by those skilled in the art that exterior surface **18** may take on many different geometries to optimize the use of implant **10** between vertebrae in different areas of the spine.

[0039] Implant **10** is manufactured by first roughly shaping first part **20** and second part **30** out of cortical and cancellous allogenic bone. Male portion **42** and female portion **44** of dovetail joint **40** are then formed in first part **20** and second part **30** respectively. Holes **28** and **38** for pin **50** are also formed in first part **20** and second part **30**. Male portion **42** is then inserted in female portion **44**, and pin **50** is inserted through holes **28** and **38**. If desired, adhesive may be used between first part **20** and second part **30**. In a preferred embodiment, pin **50** is sized so that there is a slight interference between the exterior surface of pin **50** and holes **28** and **38**. Pin **50** is thus secured in holes **28** and **38** by an interference fit between pin **50** and holes **28** and **38**. Alternatively, adhesive may be used to secure pin **50** into holes **28** and **38**. Flat sections **17** of superior surface **14** and inferior surface **16**, and exterior surface **18** are then shaped into the proper desired form. Finally, teeth **12** are formed into superior surface **14** and inferior surface **16**. In a preferred embodiment, the shaping of the parts and sections of implant **10** is performed by computer-controlled milling. However, alternative methods of forming the various parts of implant **10** may also be used.

[0040] Using the method of manufacture described above, teeth **12** are formed so that their tips are either at or below

the planes defined by the surfaces of flat sections 17. In other alternative embodiments, teeth 12 may be formed so that they extend past the planes of flat sections 17 by first forming teeth 12 on superior surface 14 and inferior surface 16 before forming flat sections 17. Furthermore, by milling teeth 12 onto the superior surface 14 and inferior surface 16 of first part 20 before joining first part 20 with second part 30, teeth 12 may be formed only from cortical bone. However, this may increase the complexity of the manufacturing process.

[0041] In order to restore the intervertebral space to the proper size after the affected disc has been removed, implant 10 has a height, h, sized to match the height of the removed disc. Typically for discectomies, h is between about 5 mm to about 12 mm, but other heights may be used.

[0042] Implant 10 may also be configured for corpectomies. In which case, it should be noted that implants 10 can be configured so that h would be approximately 10 to approximately 150 mm. Other heights may also be used. These larger sizes could be used in corpectomy, a surgical procedure in which a section of several vertebrae is removed. Implants 10 would be inserted in the space created by the removed section of bone. Due to the nature of corpectomy, an accurate preoperative determination of the size of the implant needed is very difficult. Thus, implant 10 may be cut to the proper size by the surgeon. In such cases, the implants 10 preferably would only have teeth 12 on either superior surface 14 or inferior surface 16.

[0043] A threaded hole (not shown) may be formed on either anterior end 6, lateral surface 72, or medial surface 70 of implant 10 along exterior surface 18 to receive an inserter to implant the implant between the vertebrae. Alternatively, an instrument specifically configured to hold implant 10 by fitting snugly along at least portions of exterior surface 18, for example, at anterior end 6 and portions of medial surface 70 and lateral surface 72 of implant 10 may also be used. Other means for inserting implant 10 may be used in addition to or alternatively to the methods described above.

[0044] While the embodiments described above comprise parts formed from a single piece of cortical bone and single piece of cancellous bone, it will be appreciated that multiple pieces of cortical and/or cancellous bone may be used to form the parts of an implant in accordance with the present invention. It will also be appreciated that while the embodiments described above were formed from two parts joined together, an implant formed from more than two parts is also within the spirit and scope of the present invention.

[0045] While it is apparent that the illustrative embodiments of the invention herein disclosed fulfill the objectives stated above, it will be appreciated that numerous modifications and other embodiments may be devised by those skilled in the art. Therefore, it will be understood that the appended claims are intended to cover all such modifications and embodiments which come within the spirit and scope of the present invention.

What is claimed:

- 1. An intervertebral implant having superior and inferior surfaces comprising:
 - a first part composed of cortical bone; and
 - a second part composed of cancellous bone;

wherein

the first part and the second part are connected with a dovetail joint;

the superior and inferior surfaces are formed by the combination of the first and second part; and

substantially the entire superior and inferior surfaces of the first part further comprise a plurality of teeth.

2. The implant of claim 1, wherein the teeth are arranged in a two dimensional array, with the teeth being of a pyramid shape.

3. The implant of claim 1, wherein the implant has a wedge-shaped profile to help restore disc height and spine curvature.

4. The implant of claim 2, having an anterior height which is greater than a posterior height to produce the wedge-shaped profile.

5. The implant of claim 1, wherein the top and bottom surfaces are parallel and are spaced by a distance that approximates that of an intervertebral disc.

6. The implant of claim 1, wherein the top surface is a curved surface which is contoured to mimic the end plates of the adjacent vertebrae.

7. The implant of claim 1, further comprising an exterior surface formed by the combination of the first and second parts wherein the exterior surface has been processed to a predetermined shape.

8. The implant of claim 1, wherein the implant further comprises a pin, wherein the pin connects the first part and the second part.

9. The implant of claim 1, wherein the first part and the second part are connected by an adhesive.

10. A method of manufacturing an intervertebral implant having a superior surface, an inferior surface, and an exterior surface, comprising the steps of:

forming a first part from cortical bone;

forming a second part from cancellous bone;

connecting the first part with the second part using a dovetail joint; and

forming a plurality of teeth on the superior and inferior surfaces.

11. The method of claim 10, wherein the step of forming a first part further comprises forming a male portion of the dovetail joint, and wherein the step of forming a first part further comprises forming a female portion of the dovetail joint.

12. The method of claim 11, wherein the step of forming a first part further comprises forming a hole in the male portion, and wherein the step of forming a second part further comprises forming a hole in the second part, and wherein the method further comprises the steps of:

forming a pin; and

inserting the pin through the holes in the male portion and the female portion after the first part is connected to the second part.

* * * * *